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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,871	04/13/2004	Robert J. Deleys	BJS-2551-141	3673

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EXAMINER

BLUMEL, BENJAMIN P

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,871

Applicant(s)

DELEYS ET AL.

Examiner

Benjamin P. Blumel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55,59,60,62 and 68-93 is/are pending in the application.
- 4a) Of the above claim(s) 74-76 and 90-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55,59,60,62,68-70 and 85 is/are rejected.
- 7) ☒ Claim(s) 71-73,77-84 and 86-89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2004 and 18 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☒ Certified copies of the priority documents have been received in Application No. 07/920,286.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/13/04 and 2/20/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants are informed that Benjamin P. Blumel will conduct further prosecution of the instant application, contact information is stated below.

Election/Restrictions

Applicant's election with traverse of Group I and SEQ ID NOs: 4, 12 and 16 in the reply filed on February 20, 2007 is acknowledged. The traversal is on the ground(s) that a search burden would not exist if all claims and sequences were searched since these sequences were allowed in previous patents. The traversal of the species election requirement pertaining to the claimed sequences is found persuasive and withdrawn, but the restrictions between the claimed inventions and the species election requirement with regard to the immunoassay platform are maintained for reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

Claims 74-76 and 90-93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 20, 2007.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 20, 2007 was filed after the mailing date of the Election/Restriction on January 19, 2007. The submission is in

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compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The information disclosure statement (IDS) submitted on April 13, 2004 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Continuity Data

Applicants are asked to amend the first line of the specification to update the continuity data.

Claim Objections

Claims 71-73, 77-84 and 86-89 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 55, 59, 60, 62, 68-70 and 85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 12, 19-22, 27, 32, 33 and 38 of U.S. Patent No. 6,007,982, claims 1-6, 13-15, 22, 23, 26, 39 and 40 of U.S. Patent No. 5,910,404, claims 1-6, 13-24 and 26 of U.S. Patent No. 6,872,520 B2 and claims 1-5, 7, 12 and 21-24 of U.S. Patent No. 5,922,532. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention is anticipated by the patented inventions as stated above.

Claims 55, 59, 60, 62, 68-70 and 85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, 9-11, 13-15, 17-24, 27 and 28 of U.S. Patent No. 6,287,761 B1 and claims 1, 3, 4, 6, 7 and 9-12 of U.S. Patent No. 6,576,417 B2 in view of above patented inventions. Even though '761 and '417 claim two distinct subunits of the instant invention, one skilled in the art would be motivated to combine the patented inventions of '761 and '417 with the patented inventions as mentioned above to develop the invention of the instant application.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 55, 59, 60, 62, 68-70 and 85 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Houghton et al. (US 5,350,671).

The claimed invention is drawn to a combination of three distinct peptides of HCV each consisting of a specific amino acid sequence. The first peptide comprises at least 5 amino acids from SEQ ID NOs: 1-8 or from amino acid positions 1-20, 7-26, 8-18, 13-32, 37-56, 49-68, 61-80 or 73-92. The second peptide comprises at least 5 amino acids from SEQ ID NOs: 9-15 or from amino acid positions 1688-1707, 1694-1713, 1706-1725, 1712-1731, 1718-1737, 1724-1743 or 1730-1749. The third peptide comprises at least 5 amino acids from SEQ ID NOs: 16-

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20 or the amino acid positions 2263-2282, 2275-2294, 2287-2306, 2299-2318 or 2311-2330.

The peptides are produced by either recombinant expression or by chemical synthesis, and one or more of the peptides comprises a fusion protein, which can be synthetic. The combination of peptides is also part of a kit for detecting HCV infection in a human body component by screening for reactive antibodies for the peptides of the claimed invention that are coating an immunoassay plate.

"[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it." See *In re Oelrich*, 666 F.2d at 581. Additionally, the courts have determined that "[I]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art." See *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). That is, it need not have been appreciated or recognized that the prior art reference inherently discloses the same invention for the reference to be anticipatory. See *Mehl/Biophile Int'l Corp. v. Milgraum* 192 F.3d 1362, 1365 (Fed. Cir. 1999); *Atlas Power Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

In the instant case, Houghton et al. teach the development of a peptide library of HCV. The peptides of the library could be as short as 5 amino acids. These peptides can be employed in an assay for detecting HCV specific antibodies in biological fluids and can be a fusion protein between the HCV peptide and Super Oxide Dismutase (SOD). One example of such an assay is an ELISA, in which the peptides can be added to the wells of a plate and the reactive antibodies can be detected. Some examples of amino acid ranges that contain the claimed amino acid sequences are represented below. Therefore, the teachings of Houghton et al. anticipate the claimed amino acid positions. However, even though Houghton et al. do not refer to these truncated peptides by specific SEQ ID NO: identifiers, the teachings of *In re Oelrich*, *Mehl/Biophile Intn'l Corp.*, and *Atlas Power Co.* would support the various truncated HCV peptides taught by Houghton et al. as anticipating the claimed invention of the instant application even though certain limitations were not expressly disclosed by Houghton et al. In addition, the

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conclusion of *In re Crish* 393 F3d 1253, 1364 (Fed. Cir. 2004) states that the “discovery of new properties of a known material does not make claims reciting those properties novel”.

AA-AA of Houghton et al.	Claimed Amino acid positions
AA1-AA25	1-20, 7-26
AA5-AA20	8-18
AA1-AA50	13-32
AA1-AA84	37-56
AA45-AA65	49-68
AA65-AA75	61-80
AA80-AA92	73-92
AA1690-AA1720	1688-1707, 1694-1713, 1706-1725
AA1694-AA1735	1712-1731, 1718-1737
AA1720-AA1745	1724-1743, 1730-1749
AA2265-AA2280	2263-2282
AA2275-AA2294	2275-2294
AA2290-AA2310	2287-2306, 2299-2318
AA2310-AA2330	2311-2330

Summary

No claims are allowed.

Conclusion

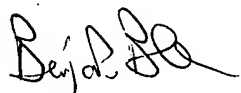
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960.

The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Benjamin Blumel
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